

FINAL WG 4, 10/12/04

**National Aquatic Animal Health Task Force-Meeting Report of Work Group 4
“Salmonids: Pathogen/Disease Program Standards”**

Twin Falls, ID. Sept. 13-15, 2004.

Introduction:

The National Aquatic Animal Health Task Force (Task Force) has been charged by the Joint Subcommittee on Aquaculture (JSA) to develop a national aquatic animal health plan (NAAHP). The purpose of the NAAHP is to: provide safe, efficient, and predictable commerce for aquatic animals; protect farmed and wild aquatic animals from the import of foreign animal diseases and pests; meet the United States' national and international aquatic animal health legal obligations; and, ensure the availability of diagnostic and certification services for private, public, and tribal aquaculture. The Task Force decided to develop the various elements of the plan in a transparent and collaborative process with its many stakeholders. The Task Force will convene work groups, which represent a broad spectrum of experts, to provide input on the various topics/elements of NAAHP. The work groups are informal in structure and are not advisory groups nor are they operating under the rules of the Federal Advisory Committee Act (FACA). Discussions of the work groups will be captured in meeting reports such as this one. These reports will in turn be used to develop draft chapters of the plan. After approval by the Task Force, the draft chapters will be submitted to JSA and stakeholders for comment. Eventually, the finalized chapters will be adopted by the Task Force as part of the NAAHP.

Participants:

Task Force: Steve Ellis (USDA/APHIS), Kevin Amos (NOAA Fisheries), and Marilyn (Guppy) Blair (USFWS).

Stakeholders: Ken Cline, Cline Trout Farms; Gary Fornshell, University of Idaho Extension; Scott LaPatra, Clear Springs Foods; Sharon MacLean, NOAA-Fisheries; Randy MacMillan, Clear Springs Foods; Peter Merrill, AVMA; Jim Parsons, Troutlodge; Gary Van Ree, Pan Fish USA; Chris Wilson, AFS-FHS.

Discussion:

The first order of business was a welcome on behalf of the entire Task Force and introductions/backgrounds of the participants. Next, an explanation was given to WG 4 on the process of NAAHP development, process for identification of work group participants, and explanation of expectations of the work group. A proposed agenda was distributed and considered by the group. The group accepted the agenda as a guideline for deliberations.

Discussion first focused on interstate commerce, States' rights, and addressing individual species groups in the context of the NAAHP. It was noted that pathogens of regional concern could be left to regional/local groups to deal with and not included in a national plan, recognizing that if a regional group chooses to regulate a disease or pathogen, they must have a surveillance and control program in place in that region. East and West NAAHP regional meetings will be scheduled next year to address aquatic animal

interstate issues with State representatives directly. In these meetings, the NAAHP will be proposed as a model for States to follow. It was also suggested that the NAAHP should address new or unknown pathogens and should provide incentives to producers for the diagnosis of unknown diseases or pathogens. It was stressed that flexibility could be a key to implementation of a NAAHP across species sectors.

A case study of APHIS' ISA program for Atlantic salmon in Maine was reviewed by Steve Ellis (See Appendix A).

The list of diseases of concern from Working Group 2 was reviewed. The concepts of Reportable Aquatic Animal Diseases (RAADs) and Program Aquatic Animal Diseases (PAADs) were discussed. Concerns over the inclusion of the North American strain of VHS on the list of PAADs were raised as North American VHSV is widely distributed on the West Coast and recently found in one fish on the East Coast and is not a serious pathogen of salmonids. It was noted that APHIS does consider strains on other livestock lists for terrestrial animals. Another issue over other countries requiring testing for nonsalmonid diseases for salmonids was also raised, i.e. this requirement does not have a scientific basis and therefore, should not be required. The question was asked why *Piscirickettsia salmonis* was not included in the PAAD list since it could potentially be found in salmonids involved in trade.

*Recommendation was made to reconsider *P. salmonis* for inclusion in PAADs, even though WG-2 did not think that *P. salmonis* met the criteria for a PAAD.

It was emphasized that the NAAHTF should be sensitive to how producers might view lists of diseases and potential costs associated with inclusion of these diseases in the NAAHP. It was also suggested that the U.S. government should pay the costs of a national surveillance program. Needed risk assessments for exotic pathogens being considered for listing as PAADs should also be identified.

Zonation

Zones were discussed as potentially being as small as an individual farm and as large as an entire country. The entire U.S. could be zoned free of EHN and OMV. Zones would be different for different pathogens and salmonid products. The suggestion was made that OIE should improve on semantics within the zonation section.

ISA:

Currently ISAV is known to exist in the U.S. only in Maine. The USFWS provides data through federal hatchery wild broodstock surveillance. Methods such as cell lines and incubation times should be reviewed, as well as historical data. On the West coast, ISA is only tested for in fish that must be certified free of ISA prior to transfer. No known transfers of live salmonids, excluding gametes, occur between the East and West coasts. ISAV has not been reported to cause disease in marine Rainbow Trout but exposed fish could be carriers. Maine's marine coastal waters and Maine's processing plants could both be considered high-risk sites for this pathogen. Processing of positive fish should stay within the positive zone until eviscerated. It was also noted that an apparently nonpathogenic strain of ISAV has been detected in farmed fish. This raises a concern similar to that of including North American VHSV as a RAAD/PAAD.

IHN:

IHN is currently found in the western U.S. (west of the Rockies) in anadromous and non-anadromous salmonids. There is no known established occurrence of IHN east of the Rockies.

IPN:

IPNV was defined to include pathogenic strains of aquatic birnaviruses. This virus has been seen throughout the U.S. but only as a very rare occurrence in the West. It has not been seen in the intermountain west for about 20 years, however, it has been seen in the Northeast including New England, North Carolina, and possibly Missouri. IPN could be said to be endemic in the U.S. with some farms free.

It was noted that there are gaps in reporting disease occurrences such as with non-APHIS approved laboratories and non-veterinarians. In addition, a suggestion was made that regional aquaculture center areas could be set up as arbitrary zones, but using waterways to define zones may make more sense.

VHS:

The European strain of VHSV is exotic to the U.S. The North American strain has been detected on the West and East coasts of the U.S. with the finding on the East coast occurring in only one fish to date.

Piscirickettsia salmonis:

P. salmonis has been detected in salmonids in Puget Sound and the coastal waters of the State of Washington. Questions were raised over current surveillance methodologies for this pathogen since it will not be detected in cell culture if antibiotics are used. Tests need to be standardized and possibly will not be repeatable due to contamination problems in cell culture.

*Some suggested that *P. salmonis* be given further consideration due to problems with surveillance and be forwarded to the research group to address these problems.

Zones determined by the NAAHP will be sent out for peer review. Concerns were raised over how to verify positive detections of pathogens. Incentives for producers to participate in the NAAHP were discussed and could include the possibility of reduced testing requirements if the producer was shown to be in a free zone for a pathogen. Concerns were also raised over States' perspectives on reduced testing schemes that may depend on buy-in of the NAAHP and how good the NAAHP is, as a model. The issue of "disease" versus "pathogen" was raised. The OIE defines "disease" in the OIE Code as both clinical and sub-clinical infection.

Surveillance

Discussions over surveillance included the comment that to verify freedom of disease, either for a zone or on a national scale, surveillance could include historical data, but the methodology and robustness of tests must be considered. A surveillance plan would need to be flexible as it may need to be modified as surveillance data becomes available. The

purpose for surveillance would include the prevention of introduction of disease, the detection of emerging or new diseases, evaluation of management practices, and assessment of the status of pathogens in wild stocks and feral broodstocks. It must include consistent standards and be continuous at some level. An example of passive surveillance would be a farmer looking at fish for morbidity and mortality. In the Maine fish health regulations, passive surveillance is defined as an elective detection that can include follow-through testing. Active surveillance would include targeted testing for specific pathogens. Again, the difference between the terms “disease” and “pathogen” and the appropriate use of either term was emphasized. Goals within a surveillance program might include non-lethal sampling techniques, lower sampling intensity over time assuming no import or environmental exposure risks, and no required testing of “dead-end” growers. Dead-end growers would include growers which do not transport live fish or eggs from their facilities except to be processed.

Data from surveillance testing should be easily sourced, with protection of confidentiality. The federal competent authorities should store, organize, and report the data. Historical health inspection data from producers, states, and federal agencies should be collected and entered into the database. With unknown funding, there should be minimum needs and optimal goals. Best Management Practices (BMPs) should be encouraged for disease control and should include assessment of the effectiveness of the BMPs.

The question was posed on whether eradication was warranted if certain diseases were found in the U.S. in free or endemic zones or if they should be managed. Opinions differed on whether to manage or eradicate ISA or IHN virus if a positive case was found in a free zone, but all participants commented in favor of managing ISA, IHN, or IPN rather than eradicate if found in an endemic zone. Matters could be complicated when considering wild endangered stocks. The same question was raised regarding exotic VHSV. There were different opinions about how best to deal with exotic VHSV should it ever be introduced in the U.S. It was suggested that criteria are needed by which a decision would be made on whether a pathogen is eradicable. Items to consider would include persistence of the pathogen in the environment, success stories of eradication programs, and the formation of expert panels on eradication. Again, pathogen versus disease would need to be defined and appropriate terms used.

Disease prevention

The use of health certificates was discussed in the working group meeting. It was determined that a three day window of inspection to shipment does not make scientific sense for eggs. In addition, the health history part of the certificate may or may not be necessary. Export certificates would need to include information needed by the receiving country, but could possibly be harmonized between countries. Import and interstate certificates would ideally be harmonized for all States. An electronic process would also be very beneficial for health certificates. A suggestion was made that the competent authorities could maintain a list of approved shippers and possibly eliminate the need for a health certificate. The need for federally accredited veterinarians to sign health certificates from a legal standpoint was also discussed.

Trade impediments

Interstate regulations were seen as potential trade impediments especially in cases of States that do not allow any live fish importations but do allow eggs. Transparent guidelines based on science and on risk assessments such as of genetics, may be necessary as a model for States to adopt. Within Idaho, import regulations currently in place (Title 50) appear to have been successful for the prevention of the introduction of exotic pathogens of salmonids. However, Title 50 did not prevent the importation of New Zealand mud snails. Exotic pests and invasive species were seen as troublesome in general. As Title 50 was developed only for salmonids, other industries may have further needs. ISA was suggested as a pathogen to add to Title 50 regulations. A question regarding the specific certification criteria of competent authorities in other countries was also raised. For example, APHIS may want to ask for a review of the competent authority status of the 15 new EU countries.

Quarantine

Quarantines should be consistent in policies between States, but should also be flexible in specifics of protocols, such as stress testing. Additional testing might be appropriate after a quarantine period, but the details of quarantine protocols should be offered elsewhere than in the NAAHP such as in an APHIS bulletin. Quarantines may be necessary in transports from high risk areas. Risk analysis, post import sampling and quarantine inspections should be components of an import plan. Cleaning and disinfection protocols could be specified if desired, however flexibility within the receiving state would be crucial.

Indemnification

Currently two insurance companies offer catastrophic policies to producers. However, insurance companies will not pay when a government depopulation order is issued. Programs of insurance with federal cooperation were discussed. USDA's indemnity programs and experiences, both generally for Foreign Animal Diseases (FADs) and specifically for ISAV were discussed. It was also noted that Colorado State has "helped" with *Myxobolus cerebralis* positive cases in disposing of fish and in building concrete ponds. Bill Cox with the State of California may be consulted in possible cases of indemnification with Koi Herpes Virus. A mandatory program may not work well, but an optional matching fund program might work. Flexibility again was emphasized in an indemnification program. The scientific and economic justification for depopulation was discussed. One working group member felt that there is considerable concern for the economic consequences of compulsory depopulation orders from any government agency, and that resolution of this issue could be a key to the success of the NAAHP.

Sanitation/Biosecurity

Flexible BMPs, egg disinfection protocols, and models or guidance for different industries could be used. HACCP could also be used as a model to identify hazards. It was also noted that the Secretary of Agriculture has extensive authority in responding to emergency situations involving livestock.

Research

Research priorities should focus on risk assessments including the rationale for management versus eradication for specific diseases. The impacts of where a disease exists and its distribution should be addressed. Information should not be collected only from literature, but also from targeted surveillance using appropriate methodologies, cell lines, etc. Temperature, pH sensitivities, effective disinfection, vectors, and reservoirs for disease should be further topics of research. Program diseases and other aquatic animal health diseases of significance such as Cold Water Disease should be addressed. Research might be directed through ARS, Sea Grant, CSREES, UI/WSU Aquaculture Research Initiative, and RAC's. Australia's extensive literature review and expert interviews could also be utilized.

*Recommend to JSA to form interagency group to prioritize research for aquatic animal health early in the process of developing the NAAHP. Specific needs should be identified for focus of research, and an industry review panel should be considered as is currently done in the Regional Aquaculture Centers (RACs). Additionally, the needs of potentially growing industries and tomorrow's pathogens should be addressed.

Emergency Training Exercises

Critical areas and action plans should be identified with industry participation. Within the APHIS program, Plum Island provides diagnostics, training, and research for Foreign Animal Diseases. The Incident Command System (ICS) is employed by APHIS in an emergency situation. Information and training on the ICS system is available at the Federal Emergency Management Agency (FEMA) website (www.fema.gov) under education and training information. APHIS depends heavily on State, military, and other agencies for critical mass in some emergency cases. Contingency planning was seen as critical with most States adopting the emergency training program developed in North Carolina. This program includes the concepts of a State Animal Response Team and a County Animal Response Team. Potential roles and challenges at state and county levels are addressed in the response team planning as well as equipment, logistics, and personnel needs. Participation in these teams was encouraged. Questions were raised of past communications between APHIS and States when addressing potential foreign animal diseases. The potential for tie-in with homeland security issues such as bioterrorism and ecoterrorism was also suggested.

Summary of issues to consider for NAAHP:

- Suggestion that *P. salmonis* be given further consideration due to problems with surveillance and be forwarded to research group to address these problems.
- Recommend to JSA to form an interagency group to prioritize research, **especially risk assessments**, for aquatic animal health early in the process of developing the NAAHP. Specific needs should be identified to focus the research, and an industry review panel should be considered as is currently done in the Regional Aquaculture Centers (RACs). Additionally, the needs of potentially growing industries and tomorrow's pathogens should be addressed.
- Specify European strain of VHSV on exotic RAAD list for the U.S.
- Strive for interstate transport regulation consistency where scientifically justified.
- Incentives needed for producers to participate in the NAAHP.

- Processing plants should be included within positive zones for pathogens.
- Appropriate uses of the terms “disease” and “pathogen” are important.
- Criteria are needed for determining whether a specific pathogen or disease is eradicable.
- Quarantine and indemnification schemes should be flexible.
- Emergency action plans should be developed with coordination between the producer, State, and Federal levels. Participation in local SART and CART teams should be encouraged in developing emergency plans.

Next Steps:

Input from WG 4 will be used in drafting portions of Chapters 5 and 6 of the NAAHP relating to program standards for salmonids. This draft portion of Chapters 5 and 6 will be completed by mid 2005. At this time there does not appear to be a need to re-convene WG 4.

Feedback from Participants (8 of 9 evaluation forms collected):

- Overall, high marks were given on organization, materials, facilities, and meeting objectives of the workshop except for comments on the room being too cold.
- Several participants remarked that their understanding and awareness of the NAAHP was greatly enhanced by this working group meeting.
- A suggestion was made to delegate representatives of the WG to draft portions of chapters of the NAAHP.
- Conference calls prior to the WG meeting could be utilized to make faster progress on NAAHP development.
- Keep the process as transparent as possible and continuous communications with the stakeholders.
- Group size perfect and well-balanced mix of participants.
- Discussions were lead rather than facilitated. More neutral facilitating suggested.
- More narrow focus or additional time needed to allow for further input.
- Facilitators kept things moving but were also flexible to address different ideas or concentrate on necessary topics. All participants had the opportunity to provide input.
- Agenda/discussions seemed to ramble and were difficult to follow in some orderly progression. Task Force is possibly trying to accomplish too much and may intimidate user groups such as private growers and existing state agencies. Suggest focusing on some do-able goals and stress the tangible benefits of the Plan to industry and States if it is to succeed.
- States' control measures and WTO implications were not addressed sufficiently. Further discussion of the relationship of the 2002 Animal Health Act and Title 50, etc. in an attempt to clarify agency roles and responsibilities would be helpful.
- Include previous completed chapters of the NAAHP in working group notebooks.
- Focus on items that will measurably benefit the commercial industry without increasing their cost of production. Since the NAAHP is not dealing with zoonotic or public health issues, it needs to be driven by industry needs. The broader the need, across species groups and life stages, the better.

Appendix A.

The USDA APHIS ISA Program

The USDA APHIS Infectious Salmon Anemia program was the first of its kind in the US aquaculture industry. It came about in response to the ISA outbreak that first appeared in farmed Atlantic salmon on New Brunswick marine farm sites in the late 1990's, and quickly spread to neighboring sites in down eastern Maine. By December 2001, Maine's salmon industry, through pressure by its Congressional delegation, veterinary and agricultural organizations and our state of Maine counterparts, convinced USDA to commit to a voluntary control program against this economically devastating disease. Earlier that year, a small group of Maine-based industry, state and federal fish health professionals had drafted a set of ISA standards in anticipation of the need for such an action plan. These standards were based on the science developed in New Brunswick and Norway, and their experiences in combating ISA. With standards drafted, a partnership between USDA APHIS and the Maine Department of Marine Resources (DMR) forged, a small team of fish biologists hired and the unanimous go-ahead from the industry in place, the program was implemented in January '02. One million sick and dead fish had already been removed prior to the program's onset, and almost all remaining sites in Cobscook Bay were seriously affected. These conditions led to the radical decision to immediately depopulate all salmon in the bay, thoroughly clean and disinfect nets, cages and equipment, fallow all sites for over 3 months and start fresh with staggered stocking between year classes at lowered stocking densities the following spring. Stocking zone and density parameters were driven by industry input. Each step in the process was discussed with site managers in advance, and trial and error within the broad scope of the standards was generally very effective. Over 1.5 million fish were removed and destroyed in 2 weeks time, using primarily rendering and occasionally composting to dispose of infected carcasses and materials. Cleaning was achieved by 2500 psi. power-washing and steam was used for disinfection. Nets were removed in closed containment and treated at land-based net treatment facilities.

Compensation, which was critical to assure industry support and survival, was paid for destroyed fish and costs associated with the cleaning and disinfection of nets and cages. Policies for calculating indemnity were negotiated and announced in advance. Other program components included: surveillance, testing, disease reporting and disease control (biosecurity). USDA relied on its state partner DMR for mandatory surveillance, quarantine, enforcement and vessel control authority. Surveillance of all salmon sites in Maine is required at least monthly, and is done by a licensed accredited veterinarian. Sampling of moribund or fresh mortalities is a critical part of the surveillance process. All samples are sent to a contract USDA APHIS-approved laboratory, and the reporting process is clearly described by DMR rule. Positive test results, together with supporting data like epidemiology, gross pathology, elevated mortality and input from company veterinarians are used to determine courses of action, as broadly specified in the standards. A small ISA technical committee, made up equally of industry and regulatory fish health professionals, guides the ISA program veterinarian on novel, contentious, confusing and other unresolved issues. Biosecurity audits are performed regularly on

marine sites, processors and vessels associated with the salmon industry. All sites are required to participate in an Integrated Pest Management (IPM) plan for the effective control of sea lice.

The program has been variably effective in controlling the disease caused by ISA virus. On sites where virus has appeared since 2003, surveillance has quickly identified troublesome cages, and harvest has been targeted to head off new infection before viral replication and fish mortality ruin farmers' chances for economic success. The political, legal, adverse weather and world market factors present in Maine have made economic success a very complex concept. The ISA program is only one factor, but must remain flexible and adaptable to new science, changing market-imposed husbandry demands, and to the influences referred to above. The ISA technical committee will meet soon to discuss amendments to the plan to keep it current and effective. Finally, because the Maine industry is so intricately linked to its New Brunswick neighbors by common owners, markets, tides and weather, communication and program coordination by farmers and regulators alike are extremely critical to the ISA plan's success and the salmon industry's survival.